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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/685,746

10/14/2003

Reid M. Rubsamen

AERX-080CIP2

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08/07/2006

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/685,746

Applicant(s)

RUBSAMEN ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006 and 31 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/31/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague for containing the term "vasodilator comprises a composition". Claim 7 depends on claim 19 which reads "A method A formulation comprising a vasodilator...". It is not clear how a formulation (or composition) comprises a composition. Also vasodilators are not considered compositions but rather active agents. The remaining claims are rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Butrous et al (EP 1 097 711).

Butrous et al teaches the use of certain **cGMP PDE5 inhibitors**, including in particular the compound **sildenafil** for the treatment of pulmonary hypertension (see abstract). Butrous also discloses that the International Patent application WO94/28902 the compound of sildenafil was found effective in treating male erectile dysfunction (see [0002]). It is also disclosed that the said compounds can be administered by **inhalation**. Inhaled formulations have advantages in delivering the active compound directly to the lung area, producing a **faster effect** than orally delivered formulations. The suitable particle size for the said aerosol is between 0.5 and 5 microns. The aerosol formulations are conveniently generated from a pressurized container, pump, spray or nebulizer with the use of a suitable propellant. For such delivery **single-dose sprays, multi-dose metered nebulizers, inhalers or atomizers can be used** (see [0023]).

Butrous also discloses that the said compounds can be administered together with other active agents such as nifedipine, diltiazem, ilprost, adenosine, nitric oxide, etc (see [0036]). The said formulations are said to be either in solution form (see [0025], [0035] and example 4) or in a micronised powder formulation and delivered by a **dry powder inhalation device** (see [0032] and example 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7-13, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butrous et al (EP 1 097 711) in view of Ellis et al (WO 9428902).

Butrous et al, discussed above, disclosed that WO 9428902 had taught treating male erectile dysfunction by cGMP PDE inhibitors such as sildenafil, but it did not teach the treatment.

WO 9428902 teaches use of compounds of cGMP PDE inhibitors such as sildenafil for treating erectile dysfunction in a male animal (see abstract, page 2, lines 10-18 and page 10, lines 19-23 and page 12, lines 1-4). The said formulations can be administered orally, sublingually or buccally (page 10, lines 32-35).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the two references to prepare aerosol formulations of cGMP PDEs such as sildenafil for treating erectile dysfunction in male patients because Butrous et al teaches inhibitory administration of sildenafil for pulmonary hypertension and Ellis et al teaches sildenafil for treating erectile dysfunction. Thus it is obvious to one of ordinary skill in the art to have prepared the inhalation formulations for treating erectile dysfunction as well as pulmonary hypertension. In other words the combination of references provides sufficient information and knowledge to one of ordinary skill in the art to make and use the invention as claimed.

Claims 2-4 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Butrous et al (EP 1 097 711) in view of Ellis et al (WO 9428902) as applied to claims 1, 5, 7-13 and 19 above, and further in view of Drug Information Handbook.

The combined references above, while disclose adding other agents to the aerosol formulations of sildenafil, lack specific disclosure on adding testosterone.

Drug Information Handbook discloses that testosterone is used for androgen replacement therapy in treating delayed male puberty (see Use). It is also disclosed that testosterone can cause penile erection (see Patient Information).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the teachings of the combined references on aerosol administration of compositions of sildenafil for treating erectile dysfunction with the disclosure of the Drug Information Handbook on use of testosterone for treating male hormone deficiencies and its effects on patients with reasonable expectations of successfully treating the said disorder by implementing a combined effect of two different active agents.

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 05/31/06 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
July 31, 2006


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